

REMARKS/ARGUMENTS

Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 are pending in the application

No amendments have been made at this time.

Applicant respectfully requests that the following remarks be made of record for purposes of Appeal.

Rejection of Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 Under 35 USC § 103(a)

Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 stand rejected under 35 USC 103(a) as being unpatentable over U.S. Patent Publication No. 2005/0025756 Erwin (hereinafter “Erwin”) further in view of Soft Gel Technologies, Inc. EP 888774 (hereinafter “Soft Gel”) and U.S. Patent Publication No. 2004/0001874 Davidson et al. (hereinafter “Davidson”). Applicant respectfully traverses the rejection for at least the following reasons.

To begin, the present invention pertains to a soft gelatin capsule that includes coenzyme Q-10 *solubilized* (dissolved) in limonene. The present invention also pertains to packaged nutraceuticals for the administration of solubilized coenzyme Q-10 in a soft gelatin capsule. This is the crux of the invention.

The soft gelatin capsule can *optionally* further include a carrier, such as bees wax, rice bran oil, or a fish oil. The soft gelatin capsule can *optionally* also further include an antioxidant. These optional components are subsumed by dependent claims; they are not included in the independent claims as the Office Action appears to make reference to on multiple occasions. This is an incorrect interpretation of the broadly claimed subject matter.

The references of record will now be addressed.

Erwin, to some degree, discloses the use of monoterpenes, such as limonene to dissolve coenzyme Q-10. The formulations Erwin discloses are liquid formulations.

Erwin fails to teach or suggest, fails to provide any motivation or an expectation of success to a person having ordinary skill in the art of any delivery means other than as a free flowing liquid, such as a syrup or elixir. Erwin is completely devoid of any teaching or suggestion, or providing any motivation or an expectation of success to a person having ordinary skill in the art to prepare a soft gelatin capsule that would encapsulate solubilized coenzyme Q-10. Such a suggestion simply does not exist in Erwin.

Erwin fails to teach or suggest, provide any motivation or an expectation of success to one of ordinary skill in the art that a solubilized solution of limonene and coenzyme Q-10 could be encapsulated *within a soft gelatin capsule*. Absent a teaching, suggestion, or providing motivation to a skilled artisan, no reference can make obvious something which is not contemplated by the reference. As such, Erwin fails to appreciate that liquid limonene/coenzyme Q-10 could be encapsulated into a soft gelatin capsule.

Soft Gel fails to remedy the deficiencies of Erwin, alone or in combination.

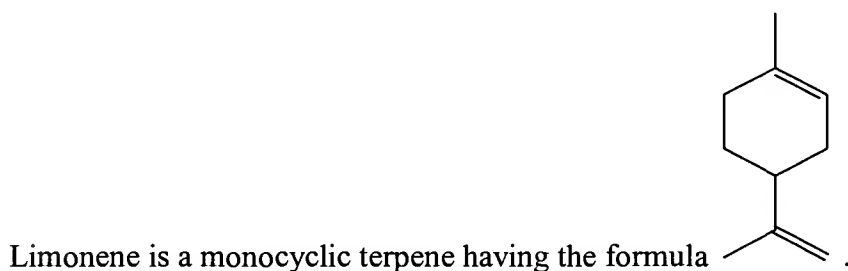
Soft Gel discloses use of rice bran oil or Vitamin E to suspend coenzyme Q-10 in the carrier (rice bran oil or Vitamin E) which is formulated into a soft gelatin capsule. Soft Gel does not teach or suggest that the rice bran oil or Vitamin E solubilizes (dissolves) coenzyme Q-10.

Soft Gel is completely devoid of any teachings of any carrier other than rice bran oil or Vitamin E. In fact Soft Gel doesn't provide any teaching or suggestion, an expectation of success or any motivation to a person having ordinary skill in the art to try any other carriers! Therefore, the teachings of Soft Gel are very limited in this respect.

Soft Gel fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to select a monoterpene, such as limonene, as a carrier *for any ingredient*.

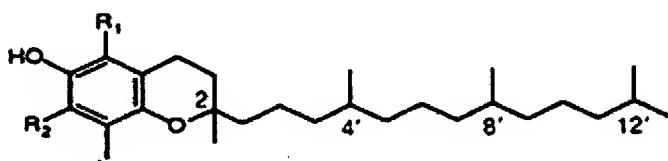
Moreover, Soft Gel fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that limonene would be a good solubilizing agent for coenzyme Q-10.

Limonene, Vitamin E and rice bran oil do not have similar chemical makeup.

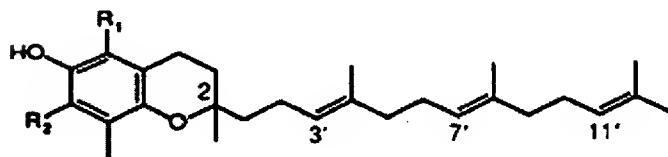


Limonene, therefore, is a an unsaturated cyclic hydrocarbyl. It is completely devoid of any other functionality other than two degrees of unsaturation.

Vitamin E is a mixture of four different tocopherols (α -, γ , δ , and β -tocopherols) and four corresponding tocotrienols:



R ¹	R ²	
CH ₃	CH ₃	α -Tocopherol
CH ₃	H	β -Tocopherol
H	CH ₃	γ -Tocopherol
H	H	δ -Tocopherol



R ¹	R ²	
CH ₃	CH ₃	α -Tocotrienol
CH ₃	H	β -Tocotrienol
H	CH ₃	γ -Tocotrienol
H	H	δ -Tocotrienol

The typical composition of rice bran oil is 81.3-84.3% triglycerides, 2-3% diglycerides, 5-6% monoglycerides, 2-3% free fatty acids, 0.3% waxes, 0.8% glycolipids, 1.6% phospholipids, 4% unsaponifiables. The fatty acid components of the glycerides are myristic, palmitic, stearic, oleic, linoleic, linolenic, arachidic, and behenic acids.

As should be noted, limonene has no carboxylic acid (or esters), no phenolic and no ether components as do the fatty acids of rice bran oil, and Vitamin E (respectively). Moreover, Vitamin E and rice bran oil are combinations of components, whereas limonene is a single material.

There is simply no teaching or suggestion, expectation of success or motivation provided to a person having ordinary skill in the art to interchange such carriers, having vastly different physical properties in terms of functionality and/or polarity in view of the differences between limonene versus rice bran oil or Vitamin.

Soft Gel fails to remedy the deficiencies of Erwin. Soft Gel only discloses use of plant oils to formulate coenzyme Q-10. Additionally, it is not clear whether the oils solubilize the coenzyme Q-10, or merely suspend the coenzyme Q-10 in a oil phase. In contrast, limonene solubilizes the coenzyme Q-10.

Neither Erwin nor Soft Gel, alone or together, teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to incorporate *solubilized* coenzyme Q-10 in limonene into a soft gelatin capsule.

Davidson does not remedy the deficiencies of either Erwin or Soft Gel, alone or in combination.

Davidson teaches much the same as Soft Gel, in that coenzyme Q-10 can be formulated in fish oil in a soft gelatin capsule. Again, it is not known whether the fish oil solubilizes the coenzyme Q-10 or merely suspends the coenzyme Q-10.

Fish oil has as its major components, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). They are polyunsaturated fatty acids or glycerides thereof. Again, these compounds contain carboxylic acids (or esters) and do not have similar structural characteristics akin to that of limonene. Again, fish oil is a combination of at least two (2) components, whereas limonene is a single material.

Davidson is completely devoid of teaching or suggestion, providing any motivation or an expectation of success to a person having ordinary skill in the art any carriers other than fish oil.

There is no teaching or suggestion, expectation of success or motivation that a person having ordinary skill in the art would consider that limonene and fish oil could be interchangeable. There is simply no teaching or suggestion in Davidson to substitute limonene for fish oil!

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to incorporate *solubilized* coenzyme Q-10 in limonene into a soft gelatin capsule.

Additionally, it appears that the arguments within the Office Action made Final essentially take the position that solubilization of any ingredient in any carrier encapsulated in a soft gelatin capsule would be obvious. This is not the correct legal standard.

This argument equates to a determination that it would be obvious to provide a carrier and any ingredient (in the future) in a soft gelatin capsule. Again, this is not the correct legal standard. The argument is not sustainable, without the requisite teaching, suggestion, or motivation provided in the reference(s) to a person having ordinary skill in the art.

It is well settled that it is not proper to selectively extract individual elements from the different contexts of different references and then combine those selectively extracted elements to arrive at a claimed combination. Rather in considering the elements within the references, the references must be considered as a whole, it being impermissible to pick and choose from a

reference only so much of it as will support a given position. *In re Wesslau*, 353, F.2d 238, 147 USPQ 391 (CCPA 1965); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). There is a rigorous requirement that there must be some motivation, suggestion or teaching of the desirability for selecting the elements and combining those elements in the specific combination of the invention, and the motivation, suggestion or teaching must be disclosed in the reference(s). *In re Kotzab*, 217 F.3d 1365, 54 USPQ2d 1308, 1316 (Fed. Cir. 2000); *In re Oetiker*, 977 F.2d 14343, 24 USPQ2d 1443 (Fed. Cir. 1992). In the absence of such motivation, suggestion or teaching, it is immaterial that some, or even all, of the elements in a specific combination of an invention are known in the prior art. As clearly stated in *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453 (Fed. Cir. 1998):

As this court has stated, “virtually all [inventions] are combinations of old elements.” *Environmental Designs, Ltd. v. Union Oil Co.*, 713F2d 693, 698,218 U.S.P.Q. (BNA) 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983) (“Most, if not all, inventions are combinations and mostly of old elements.”). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be “an illogical and inappropriate process by which to determine patentability.” *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1551,1554 (Fed. Cir. 1996).

and:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the

inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

The references cited in the Office Action made Final do not provide motivation, a suggestion or a teaching, and no showing has been made otherwise identifying in the references such a motivation, suggestion or teaching, for selecting elements from the cited references to render obvious the compositions and packaged nutraceutical recited in independent claims 14, 18 and 22, and the invention cannot be used as a blueprint for identifying a suggestion or motivation. As stated in *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 1999):

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically... the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch*, 972 F.2d 1260, 1265, 23 USP.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) (“The

invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”). In this case the Board fell into the hindsight trap.

It has been unexpectedly found that limonene solubilizes (dissolves) coenzyme Q-10 and that solubilized coenzyme Q-10 can be encapsulated into a soft gelatin capsule. This solubilized delivery of coenzyme Q-10 is more efficacious for providing bioavailable coenzyme Q-10, thus providing an unexpected advantage over dry powdered coenzyme Q-10 acid formulations.

As stated in *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001) ... "In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention." There is no suggestion, motivation, or teaching in art to select the references and combine them in a way that would produce the invention.

Additionally, as noted *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) ...there must be "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references". There simply is no objective teaching by the references of record that would lead the individual to combine the necessary teachings to provide the presently claimed invention.

Lastly, and most pointedly, *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cri. 1985) instructs that "When prior art references require *selective combination* by the court to render obvious a subsequent invention, *there must be some reason for the combination* other than the *hindsight* gleaned from the invention itself."

It appears that the Office Action made Final has done just that; used a hindsight analysis to arrive at the presently claimed invention.

It is believed that all of the issues raised in this rejection have been addressed herein. Should the Examiner maintain any of the rejections of any of the pending claims, it is respectfully requested that it be pointed out with particularity how the cited reference(s) meet each and every term of each claim with respect to which rejection is maintained, and if the rejection is based on obviousness, identification of the specific motivation, suggestion or teaching in the prior art for combining elements in the specific combination of the invention.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

No fee is believed necessary. However, if payment is needed the Commissioner is hereby authorized to charge our Deposit Account No. 04-1420 and notify us of the same.

In view of the above, Applicant respectfully submits that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested.

If a telephone conference would be helpful in resolving any remaining issues, please contact the following at 612-340-8819.

Respectfully submitted,

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April 28, 2006

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